

R E M A R K S

In the Office Action dated October 9, 2007, claims 1-4, 17 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aldefeld et al. in view of Pitrис et al. Also, claims 1-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aldefeld et al. in view of Hastings et al., further in view of Pitrис et al.

Applicants note with appreciation the telephone interview courteously afforded the undersigned representative of the Applicants on January 7, 2008, wherein the teachings of the Aldefeld et al. and Pitrис et al. references were discussed.

The Aldefeld et al. reference was the subject of a rejection in the previous Office Action dated February 12, 2007, and accordingly also was the subject of Applicants' comments in Applicants' response thereto filed on May 9, 2007. In response to those comments, the Examiner in the October 9, 2007 Office Action noted that Aldefeld et al. state in paragraph [0023] that an x-ray system is not required, but could be available and potentially utilized, as stated in paragraph [0038].

In a telephone interview, Applicants presented their position that paragraph [0038] in the Aldefeld et al. reference merely states that a standby x-ray system can be available for emergency use. Applicants submit that this is not a teaching to use such a standby x-ray system in combination with, or in place of, any of the components that are described in detail in the preceding portion of the Aldefeld et al. reference. Applicants submit that a person of ordinary skill in the field of medical imaging would understand the statements in paragraph [0038] to merely indicate that such a standby x-ray system can be available for use in the event of failure or

malfuction of any of the previously-described components, most particularly the localization device 5 that must be placed intracorporeally in the subject. If this device failed, there would then be no way to visualize the intracorporeal position of the catheter, for which purpose the standby x-ray system would then be used.

As to the statements in paragraph [0023] of the Aldefeld et al. reference, Applicants submit these are not merely statements that an x-ray system is "not required," but are statements that the system disclosed in the Aldefeld et al. reference is specifically designed to intentionally *avoid* the use of any x-ray system for any purpose. Applicants submit that the statements in paragraph [0023], particularly the last sentence thereof, is a clear and explicit teaching to a person of ordinary skill in the field of medical imaging not to make any modification to the system disclosed in the Aldefeld et al. reference that would, in fact, make use of x-rays (i.e., result in exposure of the patient to x-rays). The aforementioned statements in paragraph [0038] are clearly related to a "default" situation that would depart from the intended manner of operation of the system disclosed in Aldefeld et al., and apply only to emergency situations wherein, for some reason, the system otherwise disclosed in Aldefeld et al. is not operating as intended.

Therefore, as discussed at the interview, Applicants submit the Aldefeld et al. reference provides clear teachings *away from* using an x-ray image acquisition to identify and monitor the intracorporeal position of a catheter of an OCT image acquisition system, as disclosed and claimed in the present application.

As also discussed at the interview, the Pitriss et al. reference, in the paragraph beginning at column 19, line 12, states that insertion and placement of the fiber optic needle of the OCT imaging system disclosed therein can be guided based on data

from various types of medical diagnostic modalities, of which x-ray imaging is mentioned as a possibility. That paragraph also states that other forms of imaging, including radiography, among others, can be performed prior to, or in real-time during the fiber optic needle probe insertion, to guide the fiber optic needle probe insertion and placement.

Based on these considerations, the Examiner agreed at the interview that persuasive reasons exist against modifying the Aldefeld et al. reference in accordance with the teachings of Pitrис et al., in view of the clear intention (as expressed even in the title of the Aldefeld et al. reference) in the Aldefeld et al. reference to make no use of x-ray imaging whatsoever in the system disclosed in Aldefeld et al. (when operating as intended). Nevertheless, the Examiner stated that if this obviousness rejection based on Aldefeld et al. and Pitrис et al. were traversed in a written response, the most likely result would be that prosecution would be reopened with the Pitrис et al. reference being relied upon by itself as a basis for rejecting at least claim 1 of the present application.

Taking all of this into consideration, Applicants have determined to continue prosecution on the basis of a combination of claims 1, 5 and 16, and accordingly claim 1 has been amended to bring the subject matter of claims 5 and 16 therein, and claims 5 and 16 have been cancelled. Editorial amendments have been made in certain of the dependent claims in view of the cancellation of claim 5. An editorial amendment also has been made in claim 2 to cancel a phrase that was intended to be cancelled in Applicants' previous response, but through oversight this cancellation was not indicated.

In the October 9, 2007 Office Action, claims 5 and 16 were not among the claims that were rejected based on the Aldefeld et al. and Pitrис et al. combination. Those claims were included among the claims that were rejected based on Aldefeld et al. and Hastings et al., further in view of Pitrис et al.

Applicants acknowledge that the Hastings et al. reference discloses catheter navigation within a magnetic resonance imaging apparatus by making use of a magnetically-guided catheter. The catheter disclosed in the Hastings et al. reference, however, is not an OCT catheter, and in fact no imaging by means of any type of catheter whatsoever is disclosed in the Hastings et al. reference. The Hastings et al. reference is exclusively concerned with obtaining an image that shows the position of a treatment catheter in the context of surrounding tissue, with all of the visualization in Hastings et al. occurring exclusively by magnetic resonance imaging, with no other imaging system being employed.

The same is true of the Aldefeld et al. reference, and therefore Applicants submit that if the Aldefeld et al. reference were modified in accordance with the teachings of Hastings et al., this would merely result in a treatment catheter being localized according to the teachings of Aldefeld et al., and guided according to the teachings of Hastings et al. This still would not result in a system making use of an OCT catheter, or any other type of imaging catheter, as disclosed and claimed in the present application.

For the reasons noted above that were discussed at the interview, Applicants submit that any proposed modification of Aldefeld et al. in accordance with the teachings of Pitrис et al. (which does make use of an OCT imaging system) would be directly contrary to the teachings of Aldefeld et al., and therefore as long as the

Examiner is proposing modification of the Aldefeld et al. reference in accordance with the teachings of Pitrис et al., Applicants submit the Aldefeld et al. reference teaches away from such a combination. The additional modification of such a combination in view of the teachings of Hastings et al. would then be irrelevant, because a combination of Aldefeld et al. and Hastings et al. does not result in a system that includes all of the elements of amended claim 1 of the present application.

In view of the statements made by the Examiner in the telephone interview, it is possible the Examiner may reconsider this rejection as well, and consider reformulating the rejection so as to not to rely on the Aldefeld et al. reference at all, and to propose some sort of combination of Hastings et al. and Pitrис et al. Applicants submit the Pitrис et al. reference describes the general concept of using x-ray imaging to identify the position of an OCT catheter in a subject. The Hastings et al. reference discloses the general concept of using magnetic resonance imaging to identify the position and location of a non-imaging treatment catheter in a subject, and guiding the non-imaging treatment catheter by means of a magnetic guidance system. Applicants submit there is no teaching or suggestion in either of those references to employ x-ray imaging to provide a visualization of the intracorporeal position of an imaging catheter while simultaneously guiding the intracorporeal movement of the imaging catheter using a magnetic guidance system, as set forth in amended independent claim 1 of the present application. Applicants submit the only location where a suggestion to combine those different imaging and guidance concepts is present, in the context of using an imaging catheter, is Applicants' disclosure, and it is impermissible to use Applicants' disclosure as a hindsight basis

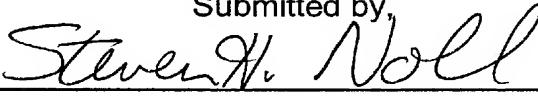
for proposing a combination of references. Applicants submit that a person of ordinary skill in the field of medical imaging and catheter guidance would assume, upon reading each of the Hastings et al. and Pitriss et al. references, that the position localization and catheter guidance disclosed in those respective references are completely suitable and adequate for the intended purposes described in those references, and there is no reason why such a person of ordinary skill would be motivated to modify either of those references in view of the teachings of the other.

The present Amendment merely rewrites dependent claims, that have already been thoroughly searched and considered by the Examiner, in independent form, and therefore the present Amendment does not raise any new issues, and is properly enterable at this stage of prosecution, after the Final Rejection.

Entry of the present Amendment and reconsideration of the application and allowance of all claims thereof are therefore respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,


(Reg. 28,982)

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